

Application Number 10/731,869
Amendment dated September 13, 2006
Responsive to Office Action mailed June 13, 2006

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REMARKS

This Amendment is responsive to the Office Action dated June 13, 2006. Applicant has amended claims 23 and 30. Claims 1-31 and 33-57 remain pending.

Rejections for Obviousness-type Double Patenting:

The Office Action provisionally rejected claims 1-31 and 33-57 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over: claims 1-23 of copending Application No. 10/731,638 (US 2004/0176817); claims 1-14 of copending Application No. 10/730,878 (US 2004/0176816); claims 1-23 of copending Application No. 10/731,699 (US 2004/0172090); claims 1-54 of copending Application No. 10/730,873 (US 2004/01766814); claims 1-27 of copending Application No. 10/731,867 (US 2004/0176673); and claims 1-2 and 14-16 of copending Application No. 10/731,868 (US 2004/0173221).

Applicant notes the provisional status of the double patenting rejections. Accordingly, Applicant will address this issue if and when the rejection is formally applied.

Restriction Under 35 U.S.C. § 101

The Office Action rejected claims 12, 21 and 53 under 35 U.S.C. § 101 as being directed to non-statutory subject matter. The Office Action specifically objected to the phrases "when the implantable medical device is implanted on the cranium," and "shaped for implantation on a cranium of a patient." Applicant respectfully traverses the rejection. As written, claims 12, 21 and 53 clearly do not claim the cranium or the patient, but instead claim an implantable medical device, which is statutory subject matter. The allegedly objectionable phrases structurally define aspects of the implantable medical device. Applicant is aware of no authority suggesting that such phrases render a claim, which is clearly directed to statutory subject matter, non-statutory. Withdrawal of this rejection is requested.

Claim Rejection Under 35 U.S.C. § 112

The Office Action rejected claim 30 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant has amended claim 30 to properly claim

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dependence from claim 28 instead of claim 27. Applicant submits that the claim, as amended, particularly points out and distinctly claims the subject matter, as required by 35 U.S.C. § 112, second paragraph.

Claim Rejections Under 35 U.S.C. § 102

The Office Action rejected claims 1-2, 11-13, 18, 20, 21-23, 35, 37-38, 41-42, 51 and 53-55 under 35 U.S.C. § 102(b) as being anticipated by U.S. 4,010,760 to Kraska et al. (Kraska). The Office Action also rejected claims 23-25, 27, 33-34, 37-41 and 56 under 35 U.S.C. § 102(e) as being anticipated by U.S. 2003/0085684 by Tsukamoto et al. (Tsukamoto). Applicant respectfully traverses these rejection to the extent such rejections may be considered applicable to the amended claims. Both Kraska and Tsukamoto fail to disclose each and every feature of the claimed invention, as required by 35 U.S.C. 102, and provide no teaching that would have suggested the desirability of modification to include such features.

Claims 1, 23, 39, 42 and 56

Independent claim 1 requires a first module that includes control electronics within a first housing, a second module that includes a second housing, and an overmold that at least partially encapsulates the first and second housings, wherein the first and second housings are coupled, and the coupling of the first and second housings allows the housings to have a plurality of degrees of freedom of movement relative to each other. Kraska fails to disclose the elements of independent claims 1, as well as the similar requirement of independent claim 23 as amended, and independent 42.

Kraska does not describe an overmold that at least partially encapsulates the first and second housings. The Office Action stated that "there is an electrically insulating biocompatible resin encapsulation 66 between module 12 and module 14."¹ The Office Action, therefore, inferred that "since the epoxy resin fills the cavity, it encapsulates both the interior of module 14 and the exterior of module 12."² However, the Examiner is incorrect in characterizing Kraska.

¹ Office Action, Page 6.

² Office Action, Page 6.

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Kraska does not disclose or suggest an electrically insulating biocompatible resin encapsulation 66 between module 12 and module 14. Instead, Kraska discloses, "Blocks 60 and 64...are set in a transparent, electrically insulating biocompatible resin encapsulant 66."³ As further indicated by the sectional view provided by Fig. 2, the blocks and the encapsulant 66 are within the housing 36 of module 14, rather than on the interior surface of the cavity 16 as presumed in the Office Action.⁴ It is evident that the blocks are inside the housing, because Kraska teaches that they define female receptacles or bores for pins or screws.⁵ There is no disclosure of encapsulant 66 to encapsulate module 14. Since encapsulant 66 is within module 14, there is no suggestion of an overmold that at least partially encapsulates the first and second housings.

Furthermore, Kraska fails to disclose or suggest that the coupling of the first and second housings allows the housings to have a plurality of degrees of freedom of movement relative to each other. The Office Action stated that "module 12 can be rotated within the cavity of module 14 in order to engage module 12 and 14."⁶ This statement is not correct. Fig. 2 of Kraska illustrates that module 12 includes pins 20 and 22 which are inserted into female receptacles 38 and 40. Pins 20 and 22 are inserted in a straight fashion, where rotating module 12 does not assist in engaging module 12 and 14. In contrast, pins 20 and 22 prevent module 12 from rotating within module 14. Kraska teaches that "the pins are widely separated on face 18 to provide a secure coupling to module 12."⁷ In addition, screw 32 is provided to couple with threaded bore 34 to connect modules 12 and 14.⁸ According to the disclosed Kraska device, modules 12 and 14 are not designed to have any degrees of freedom with respect to each other, let alone a plurality of degrees of freedom. There is no suggestion anywhere within the disclosure of Kraska that modules 12 and 14 have a plurality of degrees of freedom of movement relative to each other.

³ Kraska et al., Col. 3, ll. 7-10.

⁴ Kraska et al., Col. 2, ll. 23-24.

⁵ Kraska et al., Col. 2, ll. 58-60.

⁶ Office Action, Page 7.

⁷ Kraska et al., Col. 2, ll. 40-42.

⁸ Kraska et al., Col. 2, ll. 46-48.

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Additionally, Tsukamoto fails to disclose or suggest a hermetic interconnect member, as required by independent claim 39. The Office Action argued that lead 252 of the Tsukamoto device is a interconnect member within the meaning of claim 39. However, Tsukamoto nowhere mentions that lead 252 is or may be hermetic.

The Office Action stated, "since the interconnect member is a lead, it would necessarily be hermetic...." This statement implies that leads are necessarily hermetic. Applicant respectfully disagrees, and requests the evidence of supporting this assertion be provided.

Also, independent claim 56 requires control electronics and a rechargeable power source that provides power for the control electronics within a first housing, a recharge coil within a second housing that inductively receives energy to recharge the power source, and a flexible tether member that connects the first and second housings. Contrary to the analysis in the Office Action, Tsukamoto fails to describe the requirements of independent claim 56. According to Fig. 3b of Tsukamoto, the Tsukamoto device includes medical device 248 and IPM 238. Tsukamoto states, "[t]he medical device 248 powered by the IPM 238 is located remotely and connected for power and communication by a lead 252."⁹ There is no suggestion of control electronics and a rechargeable power source within a first housing, as IPM (implantable power module) 238 is located remotely from medical device 248. In addition, IPM 238 is similar to IPM 218 of Fig. 3a., and Tsukamoto teaches that "the battery [is] located within the hermetic case 214 of the IPM 218."¹⁰ Therefore, the elements of independent claim 56 are not described or suggested by the Tsukamoto device.

Claims 2, 11-13, 18, 20-22, 24-25, 27, 33-35, 37-38, 40-41, 51 and 53-55

Claims 2, 11-13, 18, 20-22, 24-25, 27, 33-35, 37-38, 40-41, 51 and 53-55 are allowable for at least the reasons provided above with respect to independent claims 1, 23, 39, and 42, from which they depend. A number of these dependent claims are also allowable for additional reasons. Example dependent claims are provided below.

Claim 11 requires that the overmold completely encapsulates the first and second modules. The stated position in the Office Action is that "since the overmold completely covers

⁹ Tsukamoto et al., Paragraph [0032].

¹⁰ Tsukamoto et al., Paragraph [0032].

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the interior cavity 16 of module 14 and the exterior of module 12...the overmold completely encapsulates the two modules."¹¹ Applicant is completely confused by the analysis of the Examiner for at least two reasons. First, even if the Office Action's interpretation of Kraska that encapsulant 66 covered the interior cavity 16 were correct, how can the encapsulant be considered to completely cover module 14? Second, again assuming the Office Action's incorrect interpretation of Kraska, the encapsulant would only contacting module 12 at the interface between modules 12 and 14. Moreover, in rejecting dependent claim 12, the Office Action stated that Kraska utilized a medical device with an overmold that does not encapsulate a portion of each of first and second modules. The inconsistency in these two positions with respect to claims 11 and 12 is evident.

Further, with respect claim 12, the recitations are not of intended use. Instead, the recitations further structurally limit independent claim 1 by requiring that the overmold does not encapsulate a portion of each of first and second modules. Claim 12 is further limited in that the unencapsulated portions must be proximate to the cranium when the claimed device is implanted on the cranium. These are structural limitations reciting the presence of unencapsulated portions and defining there location.

Assuming the Office Action's incorrect interpretation of Kraska, the unencapsulated portions would be opposing external surfaces of the two Kraska modules. Both surfaces could not be simultaneously proximate to the cranium and, accordingly, Kraska does not anticipate claim 12.

Claims 22, 38, 41 and 54 require that the implantable medical device is flexible such that a shape of the implantable medical device is capable of being manipulated. The Examiner rejected these claims on the basis that the recitation that an element is "capable of" performing a function does not constitute a limitation in any patentable sense. The rejection is improper according to section 2173.05(g) of the MPEP.

Accordingly, the section 2173.05(g) states that "It was held that the limitation used to define a radical on a chemical compound as 'incapable of forming a dye with said oxidizing developing agent' although functional, was perfectly acceptable because it set definite boundaries

¹¹ Office Action, Page 7.

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on the patent protection sought. *In re Barr*, 444 F.2d 588, 170 USPQ 33 (CCPA 1971).” The requirements of the claims include further limitations and boundaries on the claimed invention because the medical device must be capable of being manipulated, and is distinct from a medical device that would be incapable of being manipulated. The rejection of claims 22, 38, 41 and 54 is therefore improper, and Applicant respectfully requests that the rejection be withdrawn.

Claims 21 and 53 require that the overmold is shaped to be implanted on a cranium of a patient. The Examiner concluded that the requirements of the claims do not impart any further structural limitation over the prior art.¹² First, as determined above, Kraska fails to describe an overmold. Second, there is no description within Kraska that indicates the Kraska device is capable of being implanted on the cranium. The Kraska device is directed to a cardiac pacemaker,¹³ and the disclosure does not even contemplate implanting the Kraska device on a cranium of a patient.

Furthermore, there is no suggestion anywhere within Kraska that the Kraska device is shaped for implantation on the cranium. The Office Action stated that “nothing prevents Kraska et al. from being shaped for implantation on the cranium.”¹⁴ While the Examiner may believe that nothing prevents the Kraska device from being shaped to be implanted on the cranium, the fact remains that there is no teaching within Kraska which duplicates the elements of the claimed invention. The argument is not proper grounds for an anticipation rejection, as Kraska fails to particularly point out or disclose each limitation of claims 21 and 53.

Kraska and Tsukamoto both fail to disclose each and every limitation set forth in claims 1-2, 11-13, 18, 20-23, 24-25, 27, 33-35, 37-39, 40-42, 51 and 53-56. For at least these reasons, the Examiner has failed to establish a prima facie case for anticipation of Applicant’s claims 1-2, 11-13, 18, 20-23, 24-25, 27, 33-35, 37-39, 40-42, 51 and 53-56 under 35 U.S.C. 102. Withdrawal of these rejections is requested.

¹² Office Action, Page 8.

¹³ Kraska et al., Abstract.

¹⁴ Office Action, Page 8.

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Claim Rejections Under 35 U.S.C. § 103

The Office Action rejected claims 3-6, 8-11, 13-17, 24-26, 29-31, 42¹⁵-46, 48-50 and 57 under 35 U.S.C. § 103(a) as being unpatentable over Kraska in view of Tsukamoto. Applicant respectfully traverses the rejections to the extent such rejections may be considered applicable to the claims as amended. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Claims 3-6, 8-11, 13-17, 24-26, 29-31, 43-46, 48-50 and 57 and allowable for at least the reasons put forth with respect to independent claims 1, 23, 39, 42 and 56, from which they depend. A number of dependent claims are also allowable for additional reasons. Example dependent claims are provided below.

For example, claims 3, 24, 43 require that the power source is rechargeable, and claims 4-6, 25-26, 43-46 require a recharge coil. In support of these rejections, the Office Action characterized Kraska as disclosing the claimed invention, but that Kraska fails to disclose the rechargeable battery and recharging coil. The Office Action continued and characterized Tsukamoto as teaching a rechargeable battery and recharging coil for the purpose of supplying rechargeable power to the implantable medical device. On this basis, the Office Action concluded that it would have been obvious to modify the Kraska device in view of the Tsukamoto teachings to include a rechargeable power source and a recharge coil. The Office Action reasoned that this modification would have been desirable in order to reduce the need for invasive surgery to explant the medical device to replace the battery.

Applicant disagrees with the conclusion of obviousness. Kraska teaches away from modification to include a rechargeable power source. The entire Kraska disclosure is directed to a "detachably coupled" power source module that facilitates the exchange of the power source without affecting the remainder of the medical device.¹⁶ Modifying the power source to be rechargeable, eliminates the need of the Kraska device to include a removable power source. Since the modification would eliminate any advantage provided by the Kraska device, it would

¹⁵ Claim 42 was rejected under section 102 and not discussed with respect to the section 103 rejections. Applicant assumes its inclusion in the listing of claims rejected under section 103 was in error.

¹⁶ Kraska et al., Col. 1, ll. 28-37.

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not have been obvious to someone of ordinary skill in the art to modify the Kraska device with the teachings of Tsukamoto.

As another example, claims 7, 19, 28, 36, 47 and 52 require an overmold that at least partially encapsulates a third module. To support the rejection, the Office Action stated that Kraska fails to disclose a third module that is partially encapsulated and a lead connection module being located in the overmold. The Office Action characterized the Tsukamoto device as including a third module and the lead connection. On this basis, the Office Action concluded that it would have been obvious to someone of ordinary skill in the art to modify the Kraska device with the teachings of Tsukamoto to duplicate the elements of the claim. The Office Action reasoned that rearranging parts of an invention involves only routine skill in the art.

Applicant disagrees with the Examiner's conclusion of obviousness for multiple reasons. First, Tsukamoto fails to disclose a lead connection module. Second, there is no motivation for someone of ordinary skill in the art to modify the Kraska device with the teachings of Tsukamoto, and the Office Action relied on bad precedent in support of its conclusion that no evidence of motivation is required. Additionally, even if the Kraska device was combined with elements of the Tsukamoto device, the claimed invention would not be duplicated.

As stated in the Office Action with regard to multiple claims, Tsukamoto provides disclosure of a medical device 222, IPM 218 and lead 230 in Fig. 3a. However, there is no suggestion of a lead connection module that would be separate from the medical device or IPM. The Examiner has the burden of providing elements from the evidentiary record in order to uphold an obviousness rejection, and the Examiner has failed to do so with the prior art of Tsukamoto. Therefore, it would not have been obvious to modify the Kraska device with elements not even provided in the teachings of Tsukamoto.

Further, the propriety of the citation to *In re Japikse* is called into question by other authority cited within MPEP 2144.07. In particular *Ex parte Chicago Rawhide Mfg. Co.*, 223 USPQ 351, 353 (Bd. Pat. App. & Inter. 1984) stated that "[t]he mere fact that a worker in the art could rearrange the parts of the reference device to meet the terms of the claims on appeal is not by itself sufficient to support a finding of obviousness. The prior art must provide a motivation

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or reason for the worker in the art, without the benefit of appellant's specification, to make the necessary changes in the reference device."¹⁷

There is no motivation to someone of ordinary skill in the art to modify the Kraska device with the disclosure of Tsukamoto. There is no suggestion anywhere within the Kraska disclosure that would imply adding a third module to the Kraska device, since all necessary components are housed within modules 12 and 14. Moreover, there is no motivation to partially encapsulate the third module with an overmold. As discussed above with respect to the deficiencies of Kraska to the independent claims, only one module is partially encapsulated as module 14 is not even partially encapsulated by encapsulant 66. Therefore, there is no motivation to modify the Kraska device with one or more elements of Tsukamoto.

In addition, even if the disclosures of Kraska and Tsukamoto were combined, the resulting device would not duplicate the claimed invention. For example, if a third module and lead connector was added to the Kraska device, the elements would be located remotely from the Kraska device. Therefore, the third module and lead connector would not be at least partially covered by an overmold.

As another example, the applied references fail to disclose or suggest a flexible tether comprising a helix, as required by claims 10, 31, 50 and 57. In apparent recognition of this failure of the applied references, the Office Action argued that helix shaped leads were well known. Applicant respectfully traverses this apparent reliance on "common knowledge," and requests that evidence be entered into the record supporting the assertion that helix shaped leads were well known, as well as evidence that one of ordinary skill would have been motivated by such knowledge to provide a helix shaped tether between modules of an implantable medical device.

Further, with respect to claims 14 and 15, Applicant respectfully disagrees that an overmold of two materials would be have been obvious because it is within the general skill of a worker to select a known material based on its suitability. The present case is not one in which it is obvious to select one material as an alternative to another because they are both known to be similarly suitable for some purpose. Instead, claims 14 and 15 require that an overmold comprise

¹⁷ Emphasis added.

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two materials. The cited authority is inapplicable to the present case, and some evidence of the supposed obviousness of providing an overmold with two materials must be cited in order to support the conclusion that claims 14 and 15 are obvious.

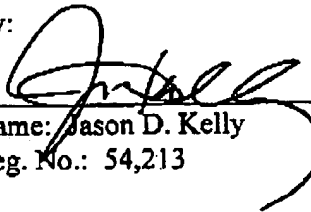
For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 3-6, 8-11, 13-17, 24-26, 29-31, 42-46, 48-50 and 57 under 35 U.S.C. 103(a). Withdrawal of this rejection is requested.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: September 13, 2006

By:


Name: Jason D. Kelly
Reg. No.: 54,213

SHUMAKER & SIEFFERT, P.A.
8425 Seasons Parkway, Suite 105
St. Paul, Minnesota 55125
Telephone: 651.735.1100
Facsimile: 651.735.1102